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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,117	07/31/2003	Hilda Elizabeth Smith	2183-6055US	5350

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TRASKBRITT, P.C.
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
02/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/632,117	SMITH, HILDA ELIZABETH	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,9,21-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) *1,6,7, 9 28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed October 10, 2009 has been entered. Claims 2-5, 8, 10-20, and 27 are canceled. Claims 1, 6-7, 9, and 28-29 are withdrawn. Claim 21 has been amended. Claim 30 has been newly added. Claims 21-26 and 30 are under consideration in this Office Action.

Response to Arguments

2. Applicant's arguments filed October 10, 2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The written description rejection of claims 21-27 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The claims are drawn to an isolated or recombinant nucleic acid molecule comprising a first nucleotide sequence of *Streptococcus suis* origin wherein the first nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate

at a pH of 7.2, wherein the nucleic acid molecule remains hybridized to the nucleotide sequence of SEQ ID NO:37 after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C.

The claims encompass a genus of isolated nucleic acids that hybridize 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized to the nucleotide sequence of SEQ ID NO:37 after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C. The specification discloses an actual reduction to practice and the complete chemical structure of the claimed genus of nucleic acids. The specification does not indicate that any nucleic acids that both hybridize to the complement of SEQ ID NO: 37. Because hybridization under the recited stringent conditions requires a high degree of structural complementarity, nucleic acids that hybridize to SEQ ID NO: 37 can share many nucleotides in common with SEQ ID NO: 37. Thus, the claimed genus necessarily includes partial structures of SEQ ID NO: 37.

However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 37 or the complement of the nucleic

acid molecule or the complement of the first nucleotide sequence that encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*.

Thus, those of ordinary skill in the art would not consider the applicant to have been in possession of the claimed genus of nucleic acids based on the disclosure. Thus, the specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of the claims.

It is noted that the issue is not whether the is written description of a nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37; rather the issue is whether there is adequate written description support for the complement of the nucleotide sequence, as recited by claim 26, which hybridizes to SEQ ID NO:37 and encodes for a portion of a FBPS of *S. suis* as recited by claim 30.

Applicants submit that complement of the of the described nucleic acid sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 under the recited conditions would have a complement that necessarily includes a nucleotide sequence that encodes for a portion of a FBPS of *S. suis.* However it is the Office's position that applicants have not provided any written description for that complement as recited by claim 26.

Contrary to Applicants assertions, the specification does not describe any FBPS of *S. suis* that are encoded by the complement of a nucleotide sequence that hybridizes

with SEQ ID NO:37 under the recited conditions. It is well known in the art that DNA that hybridizes to the DNA sequence that encodes a protein is known as complementary DNA. "Complementary" is routinely used in the art to describe the opposite (complement) strand of a given DNA sequence; however the claim reads upon an isolated or recombinant nucleic acid molecule comprising a *S. suis* nucleotide sequence where the sequence hybridizes to SEQ ID NO:37 and the complement of the nucleotide sequences encodes for a portion of a portion of FBPS. Furthermore, there is no description of the complement of the nucleotide sequence which hybridizes to SEQ ID NO:37 under the instantly claimed conditions encodes for a portion of a FBPS of *S. suis* as recited by the claims.

It is the position of the Office that the specification describes the nucleotide sequences of SEQ ID NO:37 and sequences which hybridize to SEQ ID NO:37; however that is not equivalent to a description of the complement to the hybridizing strand which encodes a portion of FBPS. There is no disclosure of a nucleic acid molecule that hybridizes to SEQ ID NO:37 wherein the complement of the hybridizing nucleotide sequence encodes for a portion of a FBPS of *S. suis.*

Applicant has not provided any guidance or working examples which would lead one of skill in the art to predict that the nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 under the instantly claimed conditions and wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis* does, in fact, encode protein product (e.g.

start sequences, methionine codon, a substantial open reading frame, stop and other termination signals). Furthermore, one of skill in the art would not predict that such a product would be structurally or functionally related to the protein with the sequence of SEQ ID NO:37, and applicant has not provided any potential means of using such an unrelated protein product, or any description of the structure or function of such a product. Therefore it appears that Applicants have failed to provide support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis.* None of the exhibits provide any written description support for a complement of the hybridizing strand that encodes a portion of a FBPS from *S. suis*. Moreover, the homology search failed to provide written description support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin.

The disclosure of SEQ ID NO: 37 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 37. However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing the complement of the nucleotide sequence that encodes for a portion of a FBPS of *S. suis* wherein the nucleotide sequence comprises which hybridizes to SEQ ID NO:37.

Thus, those of ordinary skill in the art would not consider the applicant to have been in possession of the claimed genus of an isolated or recombinant nucleic acid

molecule. Therefore the specification fails to satisfy the written description requirement of 35 U.S.C.112, first paragraph, with respect to the full scope of claims 21-27. Accordingly, Applicants arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The new matter rejection of claims 21-27 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The rejection is on the grounds that neither the specification nor originally presented claims provides support for an isolated or recombinant nucleic acid molecule comprising a first nucleotide sequence of *S. suis* origin wherein the first nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the first nucleic acid molecule remains hybridized to the nucleotide sequence of SEQ ID NO:37 after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1

mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis.*

Applicants' point to paragraphs [0078-0082] for support in the specification which expressly describes the hybridization conditions. However the new matter rejection is based on the grounds that for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 under the instantly recited hybridization conditions wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis.*

Applicants also point to paragraphs [0066] as providing a more than adequate disclosure for an isolated or recombinant nucleotide sequence that hybridizes to full length of nucleotides 89-263 SEQ ID NO:37. However, Applicant is reminded that the claims are not just drawn to a nucleotide sequence comprising a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37; rather the claims are drawn to a nucleic acid molecule wherein the complement of the hybridizing nucleotide sequence encodes for a portion of a FBPS of *S. suis.* Applicants' have not provided support for the complement.

There appears to be no teaching of an isolated or recombinant nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion FBPS of *S. suis.*

Furthermore, there is no teaching of the contiguous sequence hybridizing to the full length of nucleotides 89-263. Applicants' have not specifically pointed to teaching of the contiguous sequence hybridizing to the full length of nucleotides 89-263 of SEQ ID NO:37. Therefore, it appears that the entire specification appears to fail to recite support for the newly recited isolated or recombinant nucleotide sequence.

Despite applicants' assertions, there appears that there is no support in the specification or the claims. Therefore, applicants must specifically point to page and line number support for the identity an isolated or recombinant nucleic acid molecule comprising wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion FBPS of *S. suis* as recited by the claims. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645